EUROPEAN SOCIETY OF ONCOLOGY PHARMACY

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ESOP POSITION PAPER ON THE USE OF BIOSIMILARS IN ONCOLOGY

5th November 2021

Biosimilars are biological medicinal products for which the original patent has expired (originators or princeps), and which, like any other medicinal product, must obtain a Marketing Authorisation from the EMA for European Union or FDA for the USA guaranteeing their quality, efficacy and safety of use. Biosimilars include mostly proteins such as insulins, Granulocyte-stimulating factor (G-CSF) and glycoproteins such as erythropoietin and monoclonal antibodies (mAbs). These biosimilars are used in many pathological fields (rheumatology, dermatology, inflammatory digestive diseases) and in cancer treatments who they represent a dramatic improvement for many tumour localizations such as rituximab in onco-haematology and traztuzumab or nivolumab in solid tumours.

Considering the high cost for the health systems of these biological drugs (especially mAbs), the systematic use of their respective biosimilars is one of the most efficient ways to contains the rocketing increase of the health costs linked to cancer treatments, to increase the number of patients that can be treated for an identical expense and to permit to pay for innovative products, always more expensive. Moreover, ESOP underlines that this improved efficiency of health costs using biosimilars is especially important for low-income countries to increase the access to biologic drugs in oncology to the local population.

ESOP considers that the development of biosimilars has also induced dramatic improvements as well in the manufacture, purification, analysis and regulatory aspects of all biologicals drugs (including the innovative mAbs) as in the comprehension of drug-induced immunogenicity, mainly due to the challenging quality requirements imposed to biosimilar candidates.

Due to the high similarity with the originators, ascertained by extensive physico-chemical, biological and clinical comparison exercises required to obtain the marketing authorization, ESOP consider that biosimilars can be used with the same efficacy and safety than their respective princeps and for the same clinical indications. Thus, the interchangeability should be applied without restriction. However, due to a lack of knowledge on the biosimilars, ESOP urges the need to improve the formation of health practitioners, chiefly the prescribers, and the information of patients advocates.

ESOP believes that there are no sound scientific arguments to challenge the right of substitution of biosimilars both by community and hospital pharmacists at the initiation of treatment by a biologic drug since they are fully interchangeable. Indeed, hundred of publications, especially in real world situations, confirms no difference in efficacy and tolerance. It is obviously possible to automatically substitute a biological drug with an "identical biological" one, i.e. when a similar biological drug has the active ingredient and the

finished product coming from the same production line as the originator since the products differing only by their commercial name.

ESOP recommends thus that prescription of any biologics be mandatorily performed under their International non-proprietary name (INN) to facilitate the choice of the less expensive drugs for the hospital tenders and during the dispensation at community pharmacy level.

Moreover, since the scientific publications currently available have not demonstrated any significant difference in immunogenicity between the originators and their respective biosimilars if used in comparable clinical conditions (same patient and same pathological state), ESOP believes that the community and hospital pharmacist may also substitute them during treatment, especially in case of logistical problems such as drug shortages and introduction of new tenders. It is particularly evident for certain classes of biologic drugs such as Low molecular weight heparins (LMWH), G-CSF or EPO, largely used as adjuvant therapy in many protocols to prevent or treat side-effects of chemotherapy (anaemia, neutropenia or thrombosis). However, as a rule, it is recommended to maintain as much as possible the continuity of the initial dispensed brand if no logistical or medical reasons justify the substitution.

ESOP believes that the prescribing physician should be informed *ad posteriori* of the dispensing of any biological drug and of a substitution by a biosimilar. ESOP recommends that patients receive also appropriate information on biosimilars and substitution from the dispensing and the hospital pharmacists to improve compliance.

Finally, ESOP emphasizes the need to ensure the traceability of any biological product (princeps or biosimilar) intended to contribute to a better understanding of the clinical results of each biological drug, its undesirable side-effects, and possible problems of immunogenicity and/or loss of efficacy.